IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., a Delaware corporation, and THE CURATORS OF THE UNIVERSITY OF MISSOURI, a public corporation and body politic of the State of Missouri,	)	
Plaintiffs,	)	C.A. No. 07-827-GMS
v.	)	
PAR PHARMACEUTICAL, INC., a Delaware corporation,	)	
Defendants	)	

AMENDED ANSWER AND COUNTERCLAIMS

Defendant, Par Pharmaceutical, Inc. ("Par"), by their attorneys, hereby amends its Answer, as follows:

ANSWER

Complaint Paragraph 1: Santarus is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10590 West Ocean Air Drive, Suite 200, San Diego, California 92130. Santarus is a specialty pharmaceutical company focused on acquiring, developing and commercializing products for the prevention and treatment of gastrointestinal diseases and disorders.

Answer: On information and belief, Par admits that Santarus is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10590 West Ocean Air Drive, Suite 200, San Diego, California 92130. Par is without sufficient information to admit or deny the remaining allegations of paragraph 1 and, therefore, denies the same.

Complaint Paragraph 2: The University is a public corporation and body politic, an arm or instrumentality of state government in the state of Missouri, having a place of business at 321 University Hall, Columbia, Missouri 65211.

Answer: On information and belief, Par admits that The University of Missouri has a place of business at 321 University Hall, Columbia, Missouri 65211. Par is without sufficient information to admit or deny the remaining allegations of paragraph 2 and, therefore, denies the same.

Complaint Paragraph 3: Plaintiffs are informed and believe, and thereon allege, that Defendant is a corporation organized and existing under the laws of Delaware with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Defendant is one of the largest manufacturers and distributors of generic pharmaceutical products. Defendant conducts business throughout the United States, including in this District.

Answer: Par admits the allegations in the first and third sentences of paragraph 3. Par admits that it manufactures and distributes, *inter alia*, generic pharmaceutical products in the United States, and states that its size is a matter of public record. Par denies any remaining allegations of Paragraph 3.

Complaint Paragraph 4: This is an action for patent infringement arising under the patent laws of the United States of America, 35 U.S.C. § 1, et seq., including § 271. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

Answer: In response to the allegations of paragraph 4, Par admits that Plaintiffs purport to bring this action under Title 35, United States Code. Par states that it does not contest subject-matter jurisdiction. Par denies the remaining allegations in paragraph 4, and expressly denies any allegation of patent infringement and denies that Plaintiffs are entitled to any relief.

Complaint Paragraph 5: Defendant is subject to personal jurisdiction in this District because it is incorporated in Delaware, conducts business in this District, purposefully avails itself of the rights and benefits of Delaware law, and has substantial and continuing contacts with Delaware.

Answer: In response to the allegations in paragraph 5, Par states that it does not contest personal jurisdiction in Delaware for the purposes of this action.

Complaint Paragraph 6: Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b)-(d) and 1400(b).

Answer: In response to the allegations of paragraph 6, Par states that it does not contest venue in this judicial district for the purposes of this action.

Complaint Paragraph 7: On March 2, 2004, the United States Patent and Trademark Office (the "PTO") issued U.S. Patent No. 6,699,885, entitled "Substituted Benzimidazole Dosage Forms and Methods of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips.

Answer: In response to paragraph 7 of the complaint, Par states that the face of the '885 patent speaks for itself with respect to the date of issue, the title, and the named inventor. Par is without sufficient information to admit or deny the remaining allegations in paragraph 7, and therefore denies the same.

Complaint Paragraph 8: On or about August 22, 2005, reexamination of U.S. Patent No. 6,699,885 by the PTO was requested by a third party, which was granted by the PTO. On or about March 13, 2007, the reexamination proceedings concluded with the PTO issuing a Notice of Intent to Issue a Reexamination Certificate confirming that all claims of the patent "are determined to be patentable as amended." On September 18, 2007, the PTO issued a

Reexamination Certificate confirming that all claims as amended are "determined to be patentable." In the Reexamination Certificate, claims 1 and 26 were amended, and claims 52 and 53 were added. A copy of U.S. Patent No. 6,669,885 and its Ex Parte Reexamination Certificate (5894th) are attached hereto as Exhibits A and B, respectively, and shall be hereafter referred to collectively as the "'885 Patent."

Answer: In response to paragraph 8 of the complaint, Par admits only (1) that PTO records state that on or about August 22, 2005, a request for reexamination of the '885 Patent was filed with the PTO and was subsequently granted by the PTO, (2) on or about March 13, 2007, the PTO records indicate that the PTO issued a Notice of Intent to Issue a Reexamination Certificate, (3) PTO records indicate that on September 18, 2007, the PTO issued a Reexamination Certificate, (4) PTO records indicate that during the Reexamination proceedings, claims 1 and 26 were amended, and claims 52 and 53 were added. Par also admits that what appears to be a copy of the '885 patent is attached as Exhibit A to the complaint and what appears to be a copy of Ex Parte Reexamination Certificate (5894th) is attached to the complaint as Exhibit B. Par is denies the remaining allegations of paragraph 8.

Complaint Paragraph 9: On December 3, 2002, the PTO issued U.S. Patent No. 6,489,346 (the "'346 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. A copy of the '346 Patent is attached hereto as Exhibit C.

Answer: In response to paragraph 9 of the complaint, Par admits only that what appears to be a copy of the '346 patent is attached as Exhibit C to the complaint and states that the face of the '346 patent speaks for itself with respect to the issue date, the title and the named inventor. Par denies any remaining allegations in paragraph 9.

Complaint Paragraph 10: On November 11, 2003, the PTO issued U.S. Patent No. 6,645,988 (the "'988 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. A copy of the '988 Patent is attached hereto as Exhibit D.

Answer: In response to paragraph 10 of the complaint, Par admits only that what appears to be a copy of the '988 patent is attached as Exhibit D to the complaint and states that the face of the '988 patent speaks for itself with respect to the issue date, the title, and the named inventor. Par denies any remaining allegations in paragraph 10.

Complaint Paragraph 11: On August 24, 2004, the PTO issued U.S. Patent No. 6,780,882 (the "'882 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. A copy of the '882 Patent is attached hereto as Exhibit E.

Answer: In response to paragraph 11 of the complaint, Par admits only that what appears to be a copy of the '882 patent is attached as Exhibit E to the complaint and states that the face of the '882 patent speaks for itself with respect to the issue date, the title, and the named inventor. Par denies any remaining allegations in paragraph 11.

Complaint Paragraph 12: The University is the record owner of the '885, '346, '988, and '882 patents (collectively the "Patents-in-Suit"), and Santarus is the exclusive licensee. Plaintiffs have the right to sue to enforce the Patents-in-Suit.

Answer: Par is without information sufficient to admit or deny the allegations of paragraph 12 and, therefore, denies the same.

Complaint Paragraph 13: The Patents-in-Suit are listed in the United States Food and Drug Administration's (the "FDA") *Approved Drug Products with Therapeutic Equivalence*

Evaluations, commonly known as the Orange Book, in support of Santarus' Zegerid® (omeprazole/sodium bicarbonate) Powder for Oral Suspension 20 mg and 40 mg ("Zegerid®") products. Zegerid® is indicated for the treatment of heartburn and other symptoms of gastroesophageal reflux disease, the treatment and maintenance of healing of erosive esophagitis, and the short-term treatment of active duodenal ulcers and active benign gastric ulcers. Zegerid® is the first and only immediate-release oral proton pump inhibitor approved by the FDA. Zegerid® is marketed by Santarus.

Answer: With respect to paragraph 13 of the complaint, Par admits only that it appears that Santarus caused the Patents-in-Suit to be listed in the FDA Orange Book with respect to Santarus's Zegerid® (omeprazole/sodium bicarbonate) Powder for Oral Suspension 20 mg and 40 mg ("Zegerid®") products and that the labeling for NDA No. 21-636 approved on June 15, 2004 states that Zegerid® is indicated for the treatment of heartburn and other symptoms associated with gastroesophageal reflux disease, the short-term treatment (4-8 weeks) of erosive esophagitis which has been diagnosed by endoscopy, to maintain healing of erosive esophagitis, and the short-term treatment of active duodenal ulcer. Par is without sufficient information to admit or deny the remaining allegations of paragraph 13 and, therefore, denies the same.

Complaint Paragraph 14: On information and belief, Defendant has submitted Abbreviated New Drug Application No. 79-182 (the "ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The ANDA seeks approval to market omeprazole and sodium bicarbonate powder for oral suspension, 20 mg/1680 mg (the "Proposed 20 mg Powder") and 40 mg/1680 mg (the "Proposed 40 mg Powder"), generic versions of Zegerid®, prior to the expiration of the Patents-in-Suit.

Answer: Par admits the allegations of the first sentence of paragraph 14. Par admits that it has requested FDA to approve the ANDA before the July 16, 2016 expiration of the patents-in-suit, and that the ANDA product is omeprazole and sodium bicarbonate powder for oral suspension, 20mg/1680mg, and 40 mg/1680mg. Par denies the remaining allegations of paragraph 14.

Complaint Paragraph 15: Plaintiffs received a letter dated November 13, 2007, from Defendant notifying them that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "First Paragraph IV Certification") that, in Defendant's opinion, the Patents-in-Suit are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the Proposed 20 mg Powder.

Answer: On information and belief, Par admits the allegations of paragraph 15.

Complaint Paragraph 16: Plaintiffs received a letter dated December 6, 2007, from Defendant notifying them that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Second Paragraph IV Certification") that, in Defendant's opinion, the Patents-in-Suit are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the Proposed 20 mg and 40 mg Powder.

Answer: On information and belief, Par admits the allegations of paragraph 16.

Complaint Paragraph 17: Plaintiffs commenced this action within 45 days of receiving the First and Second Paragraph IV Certifications.

Answer: Par is without sufficient information to admit or deny the allegations of paragraph 17 and, therefore, denies the same.

Complaint Paragraph 18: Plaintiffs incorporate by reference paragraphs 1 through 17.

Answer: Par's responses to the allegations of paragraphs 1 through 17 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 19: The submission of the ANDA to the FDA, including the First and Second Paragraph IV Certifications, constitutes infringement of the '885 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed 20 mg and 40 mg Powder would infringe the '885 Patent under 35 U.S.C. § 271(a)-(c).

Answer: Par denies the allegations of paragraph 19.

Complaint Paragraph 20: Defendant has been aware of the existence of the '885 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed 20 mg and 40 mg Powder will not infringe the '885 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

Answer: Par admits that it was aware of the existence of the '885 Patent prior to filing the ANDA. Par denies the remaining allegations of paragraph 20.

Complaint Paragraph 21: Defendant's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Answer: Par denies the allegations of paragraph 21.

Complaint Paragraph 22: Plaintiffs incorporate by reference paragraphs 1 through 17.

Answer: Par's responses to the allegations of paragraphs 1 through 17 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 23: The submission of the ANDA to the FDA, including the First and Second Paragraph IV Certifications, constitutes infringement of the '346 Patent under 35 U.S.C. § 27l(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of

the Proposed 20 mg or 40 mg Powder would infringe the '346 Patent under 35 U.S.C. § 27l(a)-(c).

Answer: Par denies the allegations of paragraph 23.

Complaint Paragraph 24: Defendant has been aware of the existence of the '346 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed 20 mg and 40 mg Powder will not infringe the '346 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

Answer: Par admits that it was aware of the existence of the '346 Patent prior to filing the ANDA. Par denies the remaining allegations of paragraph 24.

Complaint Paragraph 25: Defendant's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Answer: Par denies the allegations of paragraph 25.

Complaint Paragraph 26: Plaintiffs incorporate by reference paragraphs 1 through 17.

Answer: Par's responses to the allegations of paragraphs 1 through 17 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 27: The submission of the ANDA to the FDA, including the First and Second Paragraph IV Certifications, constitutes infringement of the '988 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed 20 mg or 40 mg Powder would infringe the '988 Patent under 35 U.S.C. § 271(a)-(c).

Answer: Par denies the allegations of paragraph 27.

Complaint Paragraph 28: Defendant has been aware of the existence of the '988 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed 20 mg or

40 mg Powder will not infringe the '988 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

Answer: Par admits only that it was aware of the existence of the '988 Patent prior to filing the ANDA. Par denies the remaining allegations of paragraph 28.

Complaint Paragraph 29: Defendant's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Answer: Par denies the allegations of paragraph 29.

Complaint Paragraph 30: Plaintiffs incorporate by reference paragraphs 1 through 17.

Answer: Par's responses to the allegations of paragraphs 1 through 17 are incorporated by reference as if fully set forth herein.

Complaint Paragraph 31: The submission of the ANDA to the FDA, including the First and Second Paragraph IV Certifications, constitutes infringement of the '882 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed 20 mg or 40 mg Powder would infringe the '882 Patent under 35 U.S.C. § 271 (a)-(c).

Answer: Par denies the allegations of paragraph 31.

Complaint Paragraph 32: Defendant has been aware of the existence of the '882 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed 20 mg and 40 mg Powder will not infringe the '882 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

Answer: Par admits that it was aware of the existence of the '882 Patent prior to filing the ANDA. Par denies the remaining allegations of paragraph 32.

Complaint Paragraph 33: Defendant's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

Answer: Par denies the allegations of paragraph 33.

RESPONSE TO PRAYER FOR RELIEF

Par denies that Plaintiffs are entitled to any of the relief that they seek in their prayer for relief or otherwise.

DEFENSES

Without any admission as to the burden of proof or as to any of the allegations in the Complaint, Par states the following defenses.

First Defense

1. Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

Second Defense

2. Par's omeprazole and sodium bicarbonate capsules that are the subject of ANDA No. 79-182 (the "Proposed Products") do not infringe, and would not infringe, (directly, indirectly, contributorily or by inducement) any valid or enforceable claim of the Patents-in-Suit.

Third Defense

3. By reason of the prior art and/or statements and representations made to the United States Patent and Trademark Office during the prosecution of the application that led to the issuance of the Patents-in-Suit, the Patents-in-Suit are so limited that no claim can be construed as covering any Par activity.

Fourth Defense

4. Each and every asserted claim of the Patents-in-Suit is invalid for failure to meet one or more of the requirements of Title 35, United States Code, including Sections 101, 102, 103, and 112 and for improper double patenting.

Fifth Defense

5. Par's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Defense

6. Par has not willfully infringed any claim of the Patents-in-Suit.

Seventh Defense

7. Plaintiff's claims and requested relief are barred by the doctrine of estoppel.

Eighth Defense

8. Plaintiff's claims and requested relief are barred by the doctrine of waiver.

Ninth Defense

9. Plaintiff's claims and requested relief are barred by the doctrine of laches.

Tenth Defense

10. Every claim of U.S. Patent Numbers 6,489,346; 6,645,988; 6,699,885; and 6,780,882 is unenforceable due to the inequitable conduct of The University of Missouri and/or J. Owen Phillips, Santarus, and/or their employees, agents, attorneys, and/or others involved in the prosecution of the Patents-in-Suit.

11. Par incorporates, repeats, and reallages paragraphs 27 through 91 of its counterclaims, in which the factual basis for Par's allegations that U.S. Patent Numbers 6,489,346; 6,645,988; 6,699,885; and 6,780,882 and all their claims are unenforceable due to inequitable conduct are set forth with particularity.

WHEREFORE, Par demands judgment in its favor and against Santarus, Inc. and The Curators of the University of Missouri as follows:

(a) Dismissing the complaint with prejudice and denying each request for relief made by Santarus, Inc. and/or The Curators of the University of Missouri;

(b) Holding the '988 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(c) Holding the '346 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(d) Holding the '885 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(e) Holding the '882 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(f) Holding the '988 patent and all its claims invalid;

(g) Holding the '346 patent and all its claims invalid;

(h) Holding the '885 patent and all its claims invalid;

(i) Holding the '882 patent and all its claims invalid;

(j) Holding the '988 patent and all its claims unenforceable;

(k) Holding the '346 patent and all its claims unenforceable;

(l) Holding the '885 patent and all its claims unenforceable;

(m) Holding the '882 patent and all its claims unenforceable;

(n) Adjudging this to be an exceptional case under 35 U.S.C. § 285;

(o) Awarding Par its attorney's fees;

(p) Awarding Par its costs and expenses; and

(q) Awarding Par such other and further relief as the Court deems just and proper.

COUNTERCLAIMS

Par, by way of counterclaim against Plaintiffs, alleges:

The Parties

1. Par is a Delaware corporation with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

2. On information and belief, Santarus is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10590 West Ocean Air Drive, Suite 200, San Diego, California 92130.

3. On information and belief, The University of Missouri is a corporation having a place of business at 321 University Hall, Columbia, Missouri 65211.

Jurisdiction

4. These claims arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Par seeks declaratory relief, *i.e.*, a declaration that the Patents-in-Suit are not infringed and that they are invalid and unenforceable.

5. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. Santarus and The University of Missouri, by bringing this action in this district, have consented to and are subject to personal jurisdiction in this district.

Factual Background

7. United States Patent No. 5,840,737 ("the '737 patent"), entitled "Omeprazole Solution and Method for Using Same" was issued on November 24, 1998.

8. United States Patent No. 6,645,988 ("the '988 patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" was issued on November 11, 2003.

9. United States Patent No. 6,489,346 ("the '346 patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" was issued on December 3, 2002.

10. United States Patent No. 6,699,885 ("the '885 patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" was issued on March 2, 2004.

11. United States Patent No. 6,780,882 ("the '882 patent"), entitled Substituted Benzimidazole Dosage Forms and Method of Using Same" was issued on August 24, 2004.

12. Upon information and belief, the '737, the '988 patent, the '346 patent, the '885 patent, and the '882 patent (collectively the "Patents-in-Suit,") are assigned to The Curators of the University of Missouri.

13. United States Provisional Application No. 60/009,608 ("the Provisional Application") was filed on January 4, 1996 and is the earliest application to which the Patents-in-Suit claim priority.

14. Plaintiffs have alleged that the Patents-in-Suit are licensed to Santarus. The Patents-in-Suit purport to relate to various combinations of omeprazole and sodium bicarbonate.

15. Par submitted ANDA No. 79-182 for omeprazole to the Food and Drug Administration ("FDA").

16. Par's ANDA includes confidential information concerning Par's omeprazole capsules.

FIRST COUNT
(Declaration of Non-Infringement of the Patents-in-Suit)

17. Par repeats and realleges paragraphs 1 through 16 of the counterclaim.

18. Plaintiffs have asserted the Patents-in-Suit against Par. Plaintiffs maintain—and Par denies—that the claims of the Patents-in-Suit cover Par's Proposed Products.

19. The claims of the Patents-in-Suit do not, either literally or under the doctrine of equivalents, cover Par's Proposed Products. Thus, Par has not infringed and will not infringe any claim of the Patents-in-Suit by making, using, selling, offering for sale, marketing, or importing the Proposed Products.

20. Par and Plaintiffs have adverse legal interests, and there is a substantial controversy between Plaintiffs and Par of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the Patents-in-Suit.

21. Par is entitled to a judicial declaration that Par has not infringed and will not infringe any claim of the Patents-in-Suit by making, using, selling, offering for sale, marketing, or importing the Proposed Products.

SECOND COUNT
(Declaration of Invalidity of the Patents-in-Suit)

22. Par repeats and realleges paragraphs 1 through 21 of the counterclaim.

23. The Patents-in-Suit and all their claims are invalid under 35 U.S.C. §§ 101, 102, 103, 112, and/or for double patenting.

24. Plaintiffs maintain—and Par denies—that the Patents-in-Suit are valid.

25. Par and Plaintiffs have adverse legal interests, and there is a substantial controversy between Plaintiffs and Par of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity of the Patents-in-Suit.

26. Par is entitled to a judicial declaration that the Patents-in-Suit are invalid.

THIRD COUNT
(Declaration of Unenforceability of the Patents-in-Suit Due to Inequitable Conduct)

27. Par repeats and realleges paragraphs 1 through 26 of the counterclaim.

28. The Patents-in-Suit are unenforceable due to the inequitable conduct of The University of Missouri and/or J. Owen Phillips, Santarus, and/or their employees, agents, attorneys, and/or others involved in the prosecution of the Patents-in-Suit.

A. The Applicant Knowingly Withheld Over 150 Material Prior Art References with the Intent to Deceive the Patent Office

29. During prosecution of the '376 application, the applicant failed to disclose over 150 material prior art references with the intent to deceive the United States Patent and Trademark Office (the "Patent Office").

30. The applicant disclosed fewer than 100 material prior art references during prosecution of the '376 application.

31. However, the applicant disclosed over 250 material prior art references during prosecution of the later '207 application, which was filed on January 11, 2000. The '207 application is a parent application to each of the Patents-in-Suit.

32. These undisclosed references are prior art within the meaning of 35 U.S.C. § 102(b) to all the Patents-in-Suit as well as the Provisional Application.

33. These undisclosed references were material to a reasonable examiner.

34. The file histories of the '376 and '207 applications contain no explanation for why material prior art references disclosed in the '207 application were not disclosed during prosecution of the '376 application.

35. The applicant withheld these references with intent to deceive the USPTO. The applicant could not claim to have been ignorant of this prior art during prosecution of the '376 application because the prior art included the applicant's own work.

B. The Applicant Knowingly Withheld
His Own Presentations With Intent to Deceive the Patent Office.

36. A Supplemental Information Disclosure Statement dated December 21, 2001 from the file history of the '346 patent (the "Supplemental IDS") discloses that the applicant presented a poster in January 1994 at the Society for Critical Care Medicine Annual Meeting (the "SCCM Presentation").

37. The applicant did not disclose the SCCM Presentation or the fact that he had given the SCCM Presentation to the Patent Office during prosecution of the '376 application.

38. The applicant did not give any explanation for this omission in the '346 Supplemental IDS in the '207 application's file history or the '376 application's file history.

39. The Supplemental IDS discloses that the SCCM Presentation "related to ... SOS."

40. The Supplemental IDS states that SOS stands for "Simplified Omeprazole Solution" and that SOS "was prepared by mixing enteric coated omeprazole granules 20 mg (Prilosec®) with 10 ml of 8.4% sodium bicarbonate solution and allowing the enteric coating to dissolve before oral or nasogastric tube administration."

41. Attendees at the 1994 Society for Critical Care Medicine Annual Meeting included medical doctors who were under no obligation of confidentiality to the applicant.

42. The SCCM Presentation is prior art within the meaning of 35 U.S.C. § 102(b) to all the Patents-in-Suit as well as the Provisional Application.

43. The SCCM Presentation is a printed publication within the meaning of 35 U.S.C. § 102(b). *See In re Klopfenstein*, 380 F.3d 1345, 1348 (Fed. Cir. 2004) (holding that oral presentations given to skilled audiences are printed publications).

44. The applicant gave the SCCM Presentation in January of 1994, more than one year prior to the date that the applicant filed the Provisional Application on January 4, 1996.

45. The SCCM Presentation was material to a reasonable examiner.

46. The applicant withheld the SCCM Presentation during prosecution of the '737 patent with the intent to deceive the Patent Office.

47. The Supplemental IDS also states that the applicant gave a "Power Point presentation ... on June 11, 1994 ... entitled 'Stress-Related Mucosal Damage Optimizing Drug Therapy in the 1990's,' to the University of Missouri Surgical Society at the University of Missouri" (the "UMSS Presentation").

48. The applicant did not disclose the UMSS Presentation or the fact that he had given the UMSS Presentation to the Patent Office during prosecution of the '376 application.

49. The applicant did not give any explanation for his failure to disclose the UMSS Presentation in the Supplemental IDS.

50. The UMSS Presentation presented a "case study" using "simplified omeprazole solution" on "a 57 year old woman."

51. The UMSS Presentation is prior art within the meaning of 35 U.S.C. § 102(b) to all the Patents-in-Suit as well as the Provisional Application.

52. The UMSS Presentation is a printed publication within the meaning of 35 U.S.C. § 102(b). *See In re Klopfenstein*, 380 F.3d 1345, 1348 (Fed. Cir. 2004) (holding that oral presentations given to skilled audiences are printed publications).

53. The UMSS Presentation was given in January of 1994, more than one year prior to the date the applicant filed the Provisional Application on January 4, 1996.

54. The Provisional Application is the earliest application from which the Patents-in-Suit purport to claim priority.

55. The UMSS Presentation was material to a reasonable examiner.

56. The applicant withheld the UMSS Presentation during prosecution of the '737 patent with the intent to deceive the Patent Office.

C. The Applicant Knowingly Withheld Disclosures of His Invention to Multiple Scientists with the Intent to Deceive the Patent Office.

57. The applicant knowingly withheld from the PTO that he twice disclosed his invention to 19 scientists more than one year prior to the date he filed the Provisional Application.

58. The Supplemental IDS states that "[i]n October 1993 and in 1994," the applicant "discussed the possibility of performing a multicenter experimental study using SOS with the 'Pharmacotherapy Working Group,' a group of 19 scientists."

59. These disclosures occurred more than one year prior to the date the applicant filed the Provisional Application on January 4, 1996.

60. The applicant did not disclose these disclosures to the PTO during prosecution of the '376 application.

61. The Supplemental IDS does not state that the 19 scientists understood they were under an obligation of confidentiality to the applicant.

62. These disclosures are prior art within the meaning of 35 U.S.C. § 102(b) to all the Patents-in-Suit as well as the Provisional Application.

63. These disclosures were material to a reasonable examiner.

64. The applicant did not give any explanation for not disclosing that these disclosures took place in the Supplemental IDS.

D. The Applicant's Inequitable Conduct During Prosecution of the '737 Patent Renders All the Patents-in-Suit Unenforceable

65. On information and belief, United States Patent Application Number 08/680,376 (the "'376 Application") was the first-filed United States Utility Application to claim priority to the Provisional Application.

66. On information and belief, the '376 application was filed on July 15, 1996 and issued as the '737 Patent on November 24, 1998.

67. On information and belief, United States Patent Application No. 09/183,422 (the "'422 application") was filed on October 30, 1998 as a continuation-in-part of the '376 application and was later abandoned.

68. On information and belief, the '207 application was filed as a continuation-in-part of the '422 application on January 11, 2000 and issued as the '346 patent on December 3, 2002.

69. On information and belief, United States Patent Application No. 09/901,942 (the "'942 application") was filed on July 9, 2001as a continuation-in-part of the '207 application, and issued as the '988 patent on November 11, 2003.

70. On information and belief, United States Patent Application No. 10/260,132 (the "'132 application") was filed on September 30, 2002 as a continuation of the '207 application, and issued as the '882 patent on August 24, 2004.

71. On information and belief, United States Patent Application No. 10/054,350 (the "'350 application") was filed on January 19, 2002 as a continuation of the '942 application, and issued as the '885 patent on March 2, 2004.

72. Therefore, the '376 application is an ancestor application to every Patent-in-Suit.

73. During prosecution of the '376 application, the applicant intentionally withheld material prior art references and information with the intent to deceive the Patent Office until

almost five years after the '376 application was filed, rendering the resultant '737 patent unenforceable due to inequitable conduct.

74. In addition, the applicant's failure to disclose material prior-art references during prosecution of the '376 application creates an infectious unenforceability of the '988, '885, '882, and '346 patents.

75. There is an immediate and necessary relation between the claims of the '737 patent and the claims of the '346, '988, '885, and '882 patents.

76. Therefore, the applicant's inequitable conduct during the prosecution of the '737 patent renders the '346, '988, '885, and '882 patents unenforceable as well.

77. The claims of the '346, '988, '885, and '882 patents are not patentably distinct over the claims of the '737 patent, which issued from the '376 application.

78. The '346 patent contains a terminal disclaimer over the '737 patent.

79. The terminal disclaimer acts as an admission that the '346 patent's claims are not patentably distinct from the claims of the '737 patent.

80. The '885 patent contains a terminal disclaimer over the '737 patent and the '346 patent.

81. The terminal disclaimer acts as an admission that the '885 patent's claims are not patentably distinct from the claims of the '737 patent and the '346 patent.

82. The '882 patent contains a terminal disclaimer over the '737, '346, '988, and '885 patents.

83. Therefore, the patentee has admitted that the claims of the '882 patent and the claims of the '737, '346, '988, and '885 patents are patentably indistinct from one another.

84. The '988 patent contains a terminal disclaimer over any patent issuing from the '207 application.

85. On information and belief, the '346 patent issued from the '207 patent.

86. Therefore, the patentee has admitted that the claims of the '346 patent and the claims of the '988 patent are patentably indistinct from one another.

87. The patentee has also admitted that the claims of the '737 patent and the '346 patent are patentably indistinct from one another.

88. There is, therefore, an immediate and necessary relation between the claims of the '737 patent and the claims of the '346, '988, '885, and '882 patents.

89. The applicant also withheld material prior art references and information until almost two years after the '207 application was filed.

90. The applicant's delay in submitting this material information during prosecution of the '207 application is inequitable conduct. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995).

91. Therefore, for at least the reasons given above, the applicant's inequitable conduct during the prosecution of the '737and '346 patents renders the '737, '346, '988, '885, and '882 patents unenforceable. Par retains the right to allege new grounds of inequitable conduct as they become apparent and as more information becomes available.

92. Furthermore, Par and Plaintiffs have adverse legal interests, and there is a substantial controversy between Plaintiffs and Par of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the unenforceability of the Patents-in-Suit.

93. Par is entitled to a judicial declaration that the Patents-in-Suit are unenforceable due to inequitable conduct.

WHEREFORE, Par demands judgment in its favor and against Santarus, Inc. and The Curators of the University of Missouri as follows:

(a) Dismissing the complaint with prejudice and denying each request for relief made by Santarus, Inc. and/or The Curators of the University of Missouri;

(b) Declaring the '988 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(c) Declaring the '346 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(d) Declaring the '885 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(e) Declaring the '882 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(f) Declaring the '737 patent not infringed by the making, use, sale, offer for sale, marketing, or importation of Par's Proposed Products and not infringed by any process used to make Par's Proposed Products;

(g) Declaring the '988 patent and all its claims invalid;

(h) Declaring the '346 patent and all its claims invalid;

(i) Declaring the '885 patent and all its claims invalid;

(j) Declaring the '882 patent and all its claims invalid;

(k) Declaring the '737 patent and all its claims invalid;

(l) Declaring the '988 patent and all its claims unenforceable;

(m) Declaring the '346 patent and all its claims unenforceable;

(n) Declaring the '882 patent and all its claims unenforceable

(o) Declaring the '885 patent and all its claims unenforceable;

(p) Declaring the '737 patent and all its claims unenforceable;

(q) Adjudging this to be an exceptional case under 35 U.S.C. § 285;

(r) Awarding Par its attorney's fees;

(s) Awarding Par its costs and expenses; and

(t) Awarding Par such other and further relief as the Court deems just and proper.

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Dated: January 30, 2008

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I hereby certify that on January 30, 2008, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing(s) and Hand Delivered to the following:

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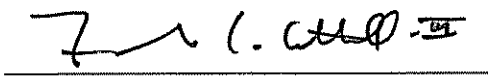

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